



HAN-006

LOCKING DEVICE FOR INTRAMEDULLARY PIN FIXATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates broadly to a system for bone fracture fixation. More particularly, this invention relates to a system and method for fixation pin stabilization within a fractured bone.

2. State of the Art

Metacarpal fractures are very common. Immobilization of the metacarpal bone on either side of the fracture is imperative for proper healing. However, the location of the fracture presents several difficulties to ideal immobilization.

The most frequently used treatments for immobilizing the fracture are splinting and casting. However, due to the location of the metacarpal bones, these treatments fail to maintain proper fracture reduction in the metacarpal bones. Strong fixation is possible with techniques using plates, fixation screws, and fixation pins attached to the affected bones through operative treatment. While these types of fracture reduction devices are commonly used in larger bone fractures, e.g., ulnar, tibial, or femoral fractures, such operative treatment generally implies a formidable incision and exposure of the fracture site. Therefore,

1 these techniques are often judged to be too invasive for the
2 relatively small and fragile metacarpal bones.

3
4 An alternative less invasive technique has been used in which
5 a small incision is made in the skin proximal the metacarpal bone,
6 a boring tool is inserted through the incision and is used to
7 drill a small hole into the metacarpal bone, the boring tool is
8 removed, and then the physician feeds the pin through the incision
9 and into the small unseen bore in the bone. However, feeding the
10 pin through the skin is often a blind operation with no manner
11 provided for indicating to the physician the relative location of
12 the pin and the small hole bored in the bone. As such, the
13 technique is objectionable to both physician and patient as blind
14 feeding can result in exacerbating damage to the surrounding
15 tissue. In addition, the implanted pin fails to provide torsional
16 fixation for fractures which need to be rotationally immobilized.
17 Similar problems exist with respect to metatarsal and phalangeal
18 fractures.

19
20 Co-owned U.S. Patent Nos. 6,200,321 and 6,273,892, which are
21 hereby incorporated by reference herein in their entireties but
22 which are not admitted as prior art hereto, disclose systems for
23 inserting pins into a metacarpal, metatarsal, phalangeal, and
24 other small bones without the drawbacks associated with blind pin
25 insertion. In addition, U.S. Patent No. 6,273,892 discloses a

1 collet which can be used to provide torsional fixation of an
2 implanted pin. However, the collet is small and difficult to
3 handle, requires a relatively large bone mass permitting an end of
4 the collet to be tapped into the bone, and is relatively time
5 consuming to implant. As such, it would be desirable to have a
6 device which provides stabilization for an implanted pin, but
7 which overcomes the stated drawbacks of the prior device.

8
9 SUMMARY OF THE INVENTION

10
11 It is therefore an object of the invention to provide a
12 device which locks a fixation pin in the metacarpal, metatarsal,
13 or phalangeal bones, or bones of similar structure.

14
15 It is another object of the invention to provide a device
16 which provides torsional and longitudinal stability to the
17 fixation pin and thereby to the bone through which the fixation
18 pin extends.

19
20 It is also an object of the invention to provide a device
21 which can be implanted relatively easily and quickly.

22
23 It is a further object of the invention to provide a fracture
24 fixation system which provides a fixation system which is
25 relatively easy to manipulate.

1 In accord with these objects, which will be discussed in
2 detail below, a locking device including a locking sleeve and a
3 handle is provided. The locking sleeve is preferably a metal
4 tubular cylindrical member having a longitudinal axis and defining
5 a channel parallel to the axis. The cylindrical member has a
6 diameter sized to receive a first portion of a fixation pin, and
7 preferably a plurality of resilient locking catches adapted to
8 hold a second portion of the fixation pin angled relative to the
9 first portion. The distal end of the sleeve includes a tip which
10 is preferably provided with a distalmost cutting edge and an
11 adjacent pin guide adapted to be located about a portion of the
12 diameter of a fixation pin. The handle is coupled to the proximal
13 end of the sleeve to facilitate manipulation of the sleeve.
14

15 The locking sleeve is used to stabilize the location and
16 orientation of a fixation pin implanted in a bone. Such an
17 implanted pin has a central portion which extends across the
18 fracture, a distal end which extends preferably to the distal end
19 of the medullary canal of the bone, and a proximal portion which
20 protrudes from the proximal end of the bone and above the skin
21 surface. The proximal portion is angled relative to the central
22 portion along a bent portion therebetween.
23

24 According to the invention, the distal end of the locking
25 sleeve is fed over the proximal end of the pin and then

1 manipulated with the handle such that the guide portion of the
2 distal end of the sleeve is placed against the pin with the
3 cutting edge against the skin. The cutting edge is then pushed to
4 pierce the skin, pass through the tissue in the hand, and enter
5 the bone surrounding the existing entry hole used for pin
6 insertion. As the locking sleeve is pushed into the tissue and
7 bone, the resilient catches of the sleeve are pushed over the bent
8 portion of the pin (generally at the intersection of the central
9 and proximal portions), with the bent portion effectively 'snap
10 fitting' between longitudinally adjacent catches as the sleeve is
11 moved thereover. The sleeve is pushed into the bone until
12 sufficiently seated for stabilized support, e.g., with the cutting
13 edge extending from one side of the medullary canal, across the
14 canal, and into the bone on the opposite side until it meets the
15 cortex. The sleeve and pin are then preferably cut below the
16 skin. Thus, the sleeve implanted in the bone stabilizes the pin
17 during healing of the fracture.

18
19 If more than one pin is used to stabilize a fracture, a
20 locking sleeve may be used for each pin.

21
22 Additional objects and advantages of the invention will
23 become apparent to those skilled in the art upon reference to the
24 detailed description taken in conjunction with the provided
25 figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a locking device for locking a pin in a bone according to the invention;

Fig. 2 is a broken top view of the distal end of the locking device of Fig. 1;

Fig. 3 is a side elevation view of the distal end of the locking device of Fig. 1;

Fig. 4 is a broken perspective view of the distal end of the locking device of Fig. 1;

Fig. 5 is a transparent schematic view of a human hand having a fractured metacarpal bone;

Fig. 6 is an enlarged view of the fractured metacarpal in Fig. 5;

Fig. 7 is a schematic illustration of the insertion of a fixation pin into the fractured metacarpal bone;

Fig. 8 illustrates insertion of the locking device into the metacarpal bone;

1 Fig. 9 illustrates the implanted locking device securing the
2 fixation pin in the metacarpal bone;

3
4 Fig. 10 is a side elevation view of the locking device
5 holding the fixation pin;

6
7 Fig. 11 is a front view of the locking device holding the
8 fixation pin; and

9
10 Fig. 12 is a perspective view of the locking device holding
11 the fixation pin.

12
13 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS
14

15 Turning now to Figs. 1 through 4, a locking device 10
16 according to the invention is shown. The locking device 10
17 includes a locking sleeve 12 and a handle 14. The locking sleeve
18 12 is preferably a metal, e.g., titanium alloy or stainless steel,
19 tubular member having a longitudinal axis A and defining a channel
20 16 parallel to the axis. The channel 16 is sized to receive a
21 portion of a fixation pin, as described in detail below. The
22 channel 16 defines an open surface 18 to the tubular member which
23 includes a plurality of spaced-apart pairs of catches 20. The
24 catches 20 define keyholes 22 which are each adapted to receive
25 another portion of a fixation pin, as also described below. Each

1 of the catches 20 preferably has ramped rear and forward sides 24,
2 26. As such, when an object, such as a portion of a fixation pin,
3 is sufficiently forced against the ramped sides of the catches,
4 the opening 18 of the channel 16 tends to widen. However, the
5 sleeve 12 is sufficiently resilient that once the force is
6 removed, the open surface 18 returns to its previous dimension.
7 The space between each catch 20 in a pair is preferably smaller
8 than the diameter of the fixation pin for which the sleeve 12 is
9 designed.

10
11 The distal end 28 of the sleeve 12 includes a distalmost
12 cutting edge 30 and an adjacent pin guide 32 which is sloped from
13 the cutting edge toward the catches.

14
15 The proximal end 34 of the sleeve 12 is preferably glued into
16 a bore (not shown) in the handle 14 with cyanoacrylate. This
17 secure coupling facilitates manipulation of the sleeve. The
18 handle is preferably molded from plastic, e.g., ABS, nylon,
19 polycarbonate, or polyethylene, but may be machined from a Delrin™
20 rod or a similar material.

21
22 According to one preferred, but only exemplar, embodiment of
23 the invention, the length of the sleeve 12 extending from the
24 handle 14 is approximately two inches. The tubular portion of the
25 sleeve 12 has an inner diameter of approximately 0.062 inches, and

1 the length from the rear of the open surface 18 to the cutting
2 edge 30 is approximately 0.6 inches. The catches 20 are
3 longitudinally spaced along 0.38 inches of the distal portion of
4 the sleeve 12, and the pin guide 32 and cutting edge 30 together
5 extend along 0.22 inches of the distal portion of the sleeve 12.
6 The catches 20 are longitudinally spaced apart by approximately
7 0.075 inches, with the space between each catch in a pair being
8 approximately 0.055 inches. The keyhole spaces 22 defined between
9 two pairs of catches is approximately 0.043 inches. The pin guide
10 32 is angled downward from the open surface 18 toward the cutting
11 edge 30 by approximately 15° , and the cutting edge 30 is angled
12 downward from the pin guide 32 by approximately 25° .

13
14 In use, the locking sleeve 12 of the device 10 is used to
15 stabilize the location and orientation of a fixation pin implanted
16 in a bone. Referring to Figs. 5 and 6, when a small elongate
17 bone, e.g., the metacarpal bone 50 of the hand 52, is broken, it
18 is desirable to stabilize the fracture 54 with a pin. Referring
19 to Figs. 6 and 7, according to any method known in the art, but
20 preferably according to the method disclosed in co-owned U.S.
21 Patent Nos. 6,200,321 and 6,273,892, already incorporated herein,
22 a fixation pin 56 is inserted in the medullary canal 58 of the
23 metacarpal bone 50. The implanted pin 56 has a central portion 60
24 which extends across the fracture 54, a distal end 62 which
25 preferably extends to the distal end of the medullary canal of the

1 bone, and a proximal portion 64 which extends from the bone 50 and
2 protrudes from the skin surface 66. The proximal portion 64 is
3 preferably bent at a 90° to 110° angle relative to the central
4 portion 60 at, along, or near a location 78 (Fig. 8) such that a
5 bent portion 79 is defined between the proximal and central
6 portions.

7
8 Turning now to Fig. 8, a locking sleeve 12 sized relative to
9 the pin so that the pin will fit in the sleeve (i.e., the inner
10 diameter of the sleeve is larger than the outer diameter of the
11 pin) then placed over the proximal end of the pin and then
12 manipulated with the handle 14 such that the guide portion 32 at
13 the distal end 28 of the sleeve 12 is placed against the pin and
14 the skin of the patient. The cutting edge 30 of the sleeve 12 is
15 then pushed to pierce the skin 66, pass through the tissue 72 in
16 the hand, and enter the bone 74 surrounding the entry hole 76
17 created during pin implantation.

18
19 Referring to Figs. 8 through 12, as the locking sleeve 12 is
20 pushed into the tissue and bone, the resilient catches 20 (Figs. 2
21 and 4) are pushed over the location 78 of the bent portion 79,
22 with the location 78 effectively 'snap fitting' into the keyholes
23 22 as the sleeve 12 is moved thereover. When the sleeve 12 is
24 sufficiently seated in the bone 74 for stabilized support
25 (preferably with the cutting edge 30 extending from one side of

1 the medullary canal, across the canal, and to the cortex on the
2 other side, as shown in Figs. 8 and 9), the sleeve and pin are
3 together cut, e.g., with a wire cutter or snips, just below the
4 skin, as shown in Fig. 9, and a bandage is preferably provided
5 over the puncture hole to aid in healing.

6
7 With the sleeve implanted in the bone as described, the pin
8 56 is stably held and prevented from both longitudinal and
9 rotational movement. Thus, the sleeve 12 stabilizes the pin 56
10 during healing of the fracture.

11
12 If more than one fixation pin is used to stabilize a
13 fracture, it is appreciated that a locking sleeve may be used for
14 each such fixation pin.

15
16 Moreover, if it is necessary to stabilize a fracture of the
17 third or fourth metacarpal bone, it is recognized that the
18 extensor tendons are located at or near the locations at which the
19 sleeve would be implanted. In order to prevent or minimize any
20 irritation which would otherwise occur should the extensor tendon
21 abrade against the cut ends of the sleeve and pin, it is
22 preferably to place a small cap 80 (Fig. 9) over the cut ends to
23 shield the extensor tendons from the cut ends. The cap 80 can be
24 made of metal or plastic, but should provide a low friction
25 interface between the tendons and the cap.

1 There have been described and illustrated herein an
2 embodiment of a locking sleeve device and method for using the
3 same. While particular embodiments of the invention have been
4 described, it is not intended that the invention be limited
5 thereto, as it is intended that the invention be as broad in scope
6 as the art will allow and that the specification be read likewise.
7 Thus, while the locking sleeve device has been particularly
8 disclosed for use in the fixation of a pin extending through a
9 fractured metacarpal bones, it will be appreciated that the device
10 may similarly be used to fixate bones of similar or smaller size
11 and for which similar problems exist with respect to fracture
12 fixation, e.g., metatarsal bones in the foot and the phalanges of
13 the fingers and toes. In addition, pediatric arm bones, e.g.,
14 ulna and radial bones, can be similarly treated. Therefore, the
15 teaching here is for the use of the locking device of the
16 invention with the above mentioned and like bones. Also, while
17 particular materials have been disclosed with respect to the
18 various components of the system of the invention, it will be
19 appreciated that other suitable materials may be used as well.
20 Furthermore, while a plurality of keyholes areas are preferably
21 defined by the sleeve, it will be appreciated that fewer (even
22 one) or more keyholes may be provided. Also, catch elements
23 having a different shape may also be used. Moreover, the catches
24 may be beveled to better accommodate and stably hold pins having
25 bends over a wide range of angles. Furthermore, a handle is not

1 required, but rather preferred to facilitate manipulation of the
2 sleeve. It will therefore be appreciated by those skilled in the
3 art that yet other modifications could be made to the provided
4 invention without deviating from its spirit and scope as claimed.

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